

REMARKS

Claims 11-21, 38, and 39 are currently pending. Claims 1-10 and 22-37 remain canceled; claims 11-18 remain withdrawn; claims 19-21, 38, and 39 have been examined on their merits; and claim 20 remains allowable.

With entry of the proposed amendments, claims 1-10 and 22-37 would remain canceled; claims 11-21 and 38-41 would be pending; claims 11-18 would remain withdrawn; and claims 40 and 41 would be added.

Proposed independent claim 40 incorporates the limitation of claim 38 into the method of claim 19. Proposed dependent claim 41 depends from claim 40 and recites the same limitation as claim 39. Support for proposed claim 40 can be found throughout the specification, *e.g.*, on page 5, lines 16-19, on page 9, lines 18-21, and in Example 7 (page 15, line 15 to page 16, line 6). Further support for proposed claim 40 and proposed claim 41 can be found in the paragraph starting on page 5, line 16 as amended in the Response filed May 19, 2006. Support for the amendments to this paragraph is supplied in the May 19th Response.

Oath/Declaration

The Examiner maintains that the declaration is defective because method claims 19-21 were not filed in the original application with the original declaration and there is no indication of record that all of the inventors listed in the original declaration are the inventors of these method claims.

Applicants submit herewith an Inventors' Declaration under 37 CFR 1.67(a) in which the previously named inventors declare that they are inventors of the pending claims. In light of this submission, Applicants respectfully ask the Examiner to withdraw his objection to the previously supplied declaration.

Claim Rejection - 35 U.S.C. §112

Claims 19 and 21 have been rejected as failing to comply with the written description requirement. Specifically, the Examiner contends that the specification does not convey that the inventors were in possession of the genus of DNA sequences encoding for a human wild-type P972 protein as recited in these claims. According to the Examiner, this genus is insufficiently disclosed by the species that are adequately disclosed in the application as filed (*i.e.*, SEQ ID NO: 1 and a nucleic acid encoding SEQ ID NO:2) because there is variation among the species of the genus and no structure/function relationship among the species of the genus disclosed in the specification.

Applicants respectfully traverse this rejection. When claiming a genus, the most recent U.S. Patent and Trademark guidelines relating to written description (66 Fed. Reg., 1099-1111, (Jan. 5, 2001)) disclose a variety of ways to meet this requirement including providing a

sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, *i.e.*, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

The guidelines state that one species may support a genus. One skilled in the art would recognize that the inventors were in possession of all of the species of the claimed genus because the application discloses several species within the genus as acknowledged by the Examiner and provides the following functional characteristics for the genus: functioning in the “growth arrest and/or DNA damage of cells” (*see* page 4, lines 6-19) and functioning to treat cancer (*see* Examples 6 and 7 on pages 14-16). Thus, the present disclosure satisfies the written description requirement as set forth in the guideline

Thus, Applicants respectfully request withdrawal of this rejection.

Claim Rejection - 35 U.S.C. §103

Claims 19, 21, 38, and 39 have been rejected as obvious over Jung *et al.* (International Publication No. WO 00/36147; "Jung") in light of Gomez-Navarro *et al.* (*European Journal of Cancer* 1999, 35:867-885; "Gomez"). The Examiner asserts that Jung contemplates using SYG972 genomic DNA encoding for the SYG972 protein to treat cancer and that the SYG972 protein is identical to the P972 protein. The Examiner concedes that Jung does not specifically teach administering a recombinant adenovirus for cancer treatment, but contends that Gomez discloses this deficiency in Jung.

Applicants respectfully traverse this rejection. A person skilled in the art would not reasonably expect based on Jung and Gomez that cancer could be treated by administering a recombinant adenovirus contain an expression vector comprising a DNA sequence encoding for a human wild-type P972 protein as set forth in the rejected claims.

Jung merely discloses a method for diagnosing cancer, but neither teaches nor suggests the anti-cancer activity of P972 or a method of treating cancer using P972 as described in the present invention. Gomez discloses a method of treating cancer in a mammal using a recombinant adenovirus comprising a nucleic acid. Gomez also teaches that p53, RB, and erbB-2 among others can be used as an anti-tumor substance by using a recombinant adenovirus as the vector (*see* page 870, Table 3 of Gomez). However, Gomez does not directly disclose that P972 can be used as the anti-tumor substance.

Although Gomez discloses using recombinant adenoviruses to perform gene therapy to treat cancer, it also reveals that transgene expression tends to be unstable in recombinant virus vectors (*see* page 876, right column, line 30) and some tumors have shown persistent tumorigenicity and proliferation after successful restoration and expression of wild-type genes (*see* 869, right column, lines 10-13).

In contrast, Figure 3 of the present application shows that MCF7 cell growth is greatly inhibited by the expression P972. Figures 4-6 of the present application also show that MCF7 cell

growth is greatly inhibited by the expression P972 and that the P972 gene has a more significant effect in terms of anti-cancer activity compared to p53. Furthermore, Example 7 and Figure 7 show that the size of a tumor transplanted into a nude mouse is greatly decreased by the administration of the AdP972 virus.

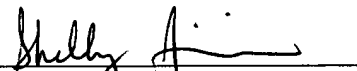
Although Jung discloses P972 and Gomez discloses that an adenovirus can be used as a vector for gene therapy to treat cancer, it is clear that Jung and Gomez do not provide a reasonable expectation of success that administering a P972 expression vector to cancer cells can treat cancer as recited in the claims. Therefore, the present invention is not obvious over Jung taken with Gomez and Applicants respectfully request withdrawal of the obviousness rejection.

Conclusion

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered, that the proposed amendment be entered, and that all pending claims be allowed and the case passed to issue. Since the amendments address the Examiner's rejections and would place the claims in condition for allowance, or at least in better form for consideration on appeal, entry is proper. If there are any other issues remaining which the Examiner believes could be resolved through a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Dated: December 5, 2006

Respectfully submitted,

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